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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions,
and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 81 FR 84583-84591, dated November 23, 2016) is amended to reflect the reorganization of the Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title for the Center for Surveillance, Epidemiology and Laboratory Service (CPN) and insert the following title which includes the Oxford comma: Center for Surveillance, Epidemiology, and Laboratory Service (CPN).

Delete in its entirety the title and the mission and function statements for the Division of Laboratory Systems (CPNB) and insert the following:

Division of Laboratory Systems (CPNB). The mission of the Division of Laboratory Systems (DLS) is to strengthen the nation's clinical and public health laboratory system by continually improving quality and safety, informatics and data science, and workforce competency.

Office of the Director (CPNB1). (1) Provides leadership and guidance on

development of strategic goals, objectives, and milestones to advance the vision and mission of the Division of Laboratory Systems (DLS), the Center for Surveillance Epidemiology and Laboratory Services (CSELS), and CDC; (2) ensures optimal planning and allocation of resources to achieve program objectives, conducts management and operations analyses, and oversees required reporting; (3) provides administrative management support, advice, and guidance to DLS regarding administrative policies, fiscal management, property management, human resources, and travel; (4) leads coordination and stewardship of DLS procurement, grants, cooperative agreements, materials management, interagency agreements, and extramural resources; (5) fosters collaborations and cross-cutting activities with other CDC components and external organizations to support the mission, activities, and operations of DLS; (6) enhances internal and external partnerships and partner/stakeholder communication; (7) provides leadership in evaluating and improving program performance, monitoring progress and accomplishments to ensure that programmatic goals are achieved with measurable impact; (8) manages issues, policy development, and tracks regulatory and legislative activities; (9) manages CDC Specimen Policy Board and the CDC/ATSDR Specimen Packaging, Inventory, and Repository (CASPIR) Advisory Committee; (10) collaborates with leadership of the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) in advancement of the Clinical Laboratory Improvement Amendments (CLIA) program and oversees CDC responsibilities therein; (11) provides scientific oversight for DLS, performing scientific review and clearance for DLS publications, presentations, and reports; (12) provides DLS communications, web support, responses to media requests, and communication outreach efforts; and

(13) coordinates requests from other CDC programs for international technical assistance among DLS capabilities.

Training and Workforce Development Branch (CPNBC). (1) Provides leadership and support of laboratory workforce through initiatives that strengthen recruitment, retention, management, and training; (2) supports the development, promotion, adoption, and implementation of competencies relevant to the laboratory workforce; (3) develops frameworks, models, and resources that support competency-based laboratory training, fellowships, and education; (4) engages agency and laboratory community experts to collaboratively assess and develop effective training products to maintain a competent, prepared, and sustainable national and global laboratory workforce; (5) designs and implements training pertaining to clinical and public health laboratory methodology, technology, quality and safety and practice for public health, clinical, CDC, and other federal agency laboratory professionals; and (6) evaluates the efficiency and effectiveness of public health laboratory education and training, including measuring the outcomes of all training to ensure the effective transfer of knowledge and skills to improved laboratory practice.

Quality and Safety Systems Branch (CPNBD). (1) Develops, promotes, implements, and evaluates intervention strategies to improve quality and safety in clinical and public health laboratory systems; (2) provides scientific and technical support for the Clinical Laboratory Improvement Amendments (CLIA) program to assure the quality, including safety, of clinical and public health laboratory testing nationwide; (3) facilitates and conducts studies to provide scientific evidence and assess the impact of CLIA regulations and voluntary guidelines for laboratory quality and safety; (4) provides

expertise and guidance in the development or revision of CLIA technical standards and voluntary guidelines for laboratory quality and safety, especially in light of new and evolving laboratory technology and practices; (5) develops, disseminates, promotes, and evaluates the impact of educational materials to support the understanding of and compliance with CLIA regulations and voluntary quality and safety guidelines; (6) hosts and manages the Clinical Laboratory Improvement Advisory Committee (CLIAC) and its workgroups on behalf of a tri-agency partnership among CDC, CMS, and FDA; (7) provides information to the laboratory medicine and public health communities, as well as policy makers, regarding the interpretation and application of the CLIA technical standards and other issues of laboratory quality and safety; (8) provides technical assistance in the review of laboratory accreditation and state licensure programs, and CLIA-approved proficiency testing programs; (9) facilitates and supports collaborations with federal partners and other stakeholders (including other CDC programs upon request) for the exchange of information about laboratory quality and safety practices, research, standards, and guidelines, and coordinates clinical and public health laboratory improvement efforts among all; (10) provides safety and quality subject matter expertise to the Training and Workforce Development Branch for the development of training courses for internal CDC laboratories and external clinical and public health laboratories; (11) provides advice and oversight of safety and quality measures, controls, practices and documents to ensure compliance of DLS laboratory areas with CDC policies, regulations, and guidelines for laboratory quality and safety (e.g., Roybal campus – Building 18 Training Laboratory and Lawrenceville campus laboratories); (12) provides scientific and technical support and guidance for CDC initiatives, programs, committees, work groups,

and task forces involving use, handling, shipping, import/export, transport or storage of biological specimens and their support materials; (13) provides safety and quality-related content expertise for the development of the Laboratory Leadership Service (LLS) Fellows curriculum and serve as course instructors for LLS training classes (and to other laboratory-related workforce efforts as may be requested by other programs); and (14) serves as quality and safety advisors and liaisons to other CDC programs and offices involving clinical laboratory activities upon request.

Informatics and Data Science Branch (CPNBE). (1) Supports the CDC Specimen Policy Board and OADLSS in the development of CDC specimen management and collection policies, and oversees implementation of those policies at CASPIR in collaboration with the CASPIR Advisory Committee; (2) develops, promotes, implements, and evaluates data science approaches for improved research of large and complex data sets in support of CLIA standards and laboratory practice; (3) maintains and leverages data acquired from national laboratory systems and other large health databases to evaluate laboratory testing events, capabilities, capacity, and public health outcomes; (4) develops solutions to strengthen the management of laboratory test service capability and capacity data, biorepositories, access to materials for standardizing laboratory testing, as well as support laboratory preparedness and workforce development activities; (5) develops and implements solutions, often with external partners and collaborators, to strengthen clinical and public health laboratory information systems, reporting of laboratory results between diagnostic facilities and healthcare providers, electronic reporting of laboratory information to electronic health records, and general preparedness of the laboratory system to respond to public health emergencies;

(6) develops and implements computer-based decision support tools and mobile applications that help to inform better laboratory-related decision-making by healthcare providers; and (7) collaborates with other CDC programs to develop and promote informatics solutions for improving laboratory management, practice, and preparedness.

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